

REMARKS

Upon entry of the amendments, claims 59-93 are canceled and claims 94-113 are added to more clearly define Applicants' invention. The amendments do not introduce any new matter within the meaning of 35 U.S.C. §132. Accordingly, entry of the amendments is respectfully requested.

1. Claim Objections

In the Office Action, the Examiner states:

Claims 61 and 62 are duplicates of each other. The Examiner respectfully requests that one of these claims be cancelled or amended to distinguish them.

The term "intercellular" is spelled incorrectly in claim 60.

Applicants have canceled claims 60, 61 and 62 and thus obviating grounds for this objection. Further, Applicants respectfully point out that newly added claim 96 is directed to the promotion of the formation of connexin, while new claim 97 is directed to the promotion of the formation of connexin 43. Therefore, claims 96 and 97 are not redundant.

In view of the foregoing, Applicants respectfully request the Examiner to withdraw the claim objections.

2. Rejection Under 35 U.S.C. §112, first paragraph

Claims 79-93 are rejected under 35 U.S.C. §112, first paragraph, as failing to comply with the enablement requirement.

In the Office Action, the Examiner states:

The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention...

(1) The nature of the invention:

The invention is directed toward a method of promoting and/or increasing the activity of a cosmetic agent acting directly in the cell or via intracellular second messengers, comprising the application of a cosmetic agent to the skin areas of a person in need thereof, of an effective amount of at least one substance promoting intercellular communication.

(2) The state of the prior art:

The prior art is filled with cosmetic agents which promote intercellular communication, as most transdermally applied cosmetic agents are absorbed by the epidermis and other layers of skin and then transported across veins and arteries (blood vessel wall cells) in the blood stream or are absorbed by the epidermis which affects the dermis and other skin layers. For example see US 5,811,083 which teaches a topically applied composition that has its effects on the dermis, though the topical application occurs on the epidermis. However, the art is silent in regard to agents, whose activity is increased or promoted by being used in conjunction with active compounds that promote intercellular communication.

(3) The relative skill of those in the art:

The relative skill of those in the art is high, as one of skill cannot predict how one compound will affect another compound or a physiological process when applied to the skin of a live person.

(4) The predictability or unpredictability of the art:

The unpredictability of the cosmetic art is very high, as it is impossible to know how two or more chemical compounds will behave in vivo and how their composition will affect one another and an in vivo physiological process.

(5) The breadth of the claims:

The claims are very broad. The cosmetic agent can be anything and the substance promoting intercellular communication encompasses an incredible number of compounds because, as described above, most every topically applied cosmetic agent promotes intercellular communication.

(6) The amount of direction or guidance presented

The instant specification provides no guidance or direction as to what these cosmetic agents are or can be. The method is merely stated.

(7) The presence or absence of working examples:

The instant specification provides no working examples of the method of claim 79.

(8) The quantity of experimentation necessary:

Since it is impossible to predict the physiological effect of bringing two chemical compounds together, an incredible amount of experimentation would be required to determine what cosmetic agents and what substances can be combined to produce an increase in the activity/effect of the cosmetic agent.

Applicants have canceled claims 79-93, and thus obviating grounds for this rejection. Therefore, the Examiner is respectfully asked to reconsider and withdraw this rejection.

3. Rejection Under 35 U.S.C. §112, second paragraph

Claims 59-78 and 91 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite. In the Office Action, the Examiner states:

(i) The phrase "for obtaining an anti-ageing effect on said skin areas, for improving the firmness and elasticity of the skin, for delaying the appearance of wrinkles or for reducing their depth" in claim 59 (lines 3-6) is vague and indefinite, as it is confusing. Are not improving firmness and elasticity of the skin and delaying the appearance of wrinkles and reducing their depth, anti-ageing effects? Is Applicant claiming a range within a range?

(ii) The phrase "said substance is presenting cosmetic composition" in claim 64 is vague and indefinite, as it is confusing. What does this phrase mean?

(iii) Claim 71 recites the limitation "the composition of claim 65" in line 1. There is insufficient antecedent basis for this limitation in the claim.

(iv) Claim 76 and 91 are vague and indefinite, as the scope of the claims is unascertainable. How can the conditions both comprise and consist essentially of? This is confusing.

Applicants have canceled claims 59-78 and 91 and thus obviating grounds for this rejection. Therefore, Applicants respectfully request the Examiner to reconsider and withdraw this rejection.

4. Rejection of Under 35 U.S.C. §102(b)

Claim 59 is rejected under 35 U.S.C. §102(b) as being anticipated by Pelle et al., U.S. 5,811,083. In the Office Action, the Examiner states:

Pelle et al. disclose in Col. 13, line 14-Col. 14, line 6, a method for treating or retarding lipid peroxidation-medicated skin aging in a patient which comprises topically administering to skin of a patient in need thereof a composition comprising a lipid peroxidation inhibiting amount of a tocopherol derivative. Col. 2, lines 36-37, teach the tocopherol derivative of Col. 13-14, as a novel tocopherol compound with enhanced antioxidant activity.

Applicants respectfully traverse this rejection. The test for anticipation is whether each and every element as set forth in the claims of the application at issue is found, either expressly or inherently described, in a single prior art reference. *Verdegaal Bros. V. Union Oil Co. of California*, 2 U.S.P.Q.2d 1051, 1053 (Fed. Cir. 1987); MPEP §2131. The identical invention must be shown in as complete detail as is contained in the claim. *Richardson v. Suzuki Motor Co.*, 9 U.S.P.Q.2d 1913, 1920 (Fed. Cir. 1989); MPEP §2131. Furthermore, the elements must be arranged as required by the claim. *In re Bond*, 15 U.S.P.Q.2d 1566 (Fed. Cir. 1990).

Applicants have canceled claim 59 and added new claim 94 in order to more clearly define the present invention. Applicants respectfully state that Pelle et al. do not teach a method for promoting intercellular communication as presently claimed. Intercellular communication has nothing to do with the classical means, which are used to improve transdermal penetration of a substance. Among the classical vectors for improving intracutaneous or percutaneous penetration, alcohol is the most well known in the art. It is known that such vectors enable substances to cross the barrier constituting the upper layers of

the skin. Such a mechanism is completely different from the new method according to the present invention, which enables the improvement or restoration of intercellular communication, especially via the gap junction. See specification pages 2-3, and example III.

Accordingly, each and every element of the present invention is not taught in the cited reference, and Applicants respectfully request the Examiner to reconsider and withdraw the rejection.

5. Rejection of Under 35 U.S.C. §103(a)

Claims 59-93 are rejected under 35 U.S.C. §103(a) as being unpatentable over Briand (English Translation of FR 2,657,012) in view of Winget, U.S. Patent No. 5,767,095. In the Office Action, the Examiner states:

The instant invention is directed toward a method of skin care comprising applying to skin areas of a person in need thereof, an effective amount of at least one substance promoting intercellular communication for obtaining an anti-ageing effect, improving firmness and elasticity of skin, delaying the appearance of wrinkles, or reducing their depth, and a method of promoting and/or increasing the activity of a cosmetic agent acting directly in the cell or via intracellular second messengers, comprising the application of a cosmetic agent to the skin areas of a person in need thereof, of an effective amount of at least one substance promoting intercellular communication.

Briand teaches the use of microscopic algae extracts for the preparation of cosmetics, wherein the extracts have free radical reducing activity, wherein a decrease in free radical production is established in the art to reduce aging, see page 2. Skeletonema is specifically taught as a preferred extract, see page 3. The cosmetics are taught as compositions comprising algae extracts and additional cosmetic ingredients/agents for treating the skin, see page 12. External application is specifically taught, see page 12. Exemplified is a composition comprising 3% extract of Skeletonema. Briand does not teach Skeletonema as a complete lipid extract, as

water and an organic solvent art (ethanol and isopropanol) are taught as the extraction medium for Skeletonema.

Winget teaches anti-inflammatory compositions containing a purified microalgal lipid preparation for application to the skin. Skeletonema is specifically taught as a preferred algae. Such extracts are taught as imparting potent anti-inflammatory effects to the skin of a user. See Col. 1, line 19-Col. 2, line 55; Col. 10, lines 9-66.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to incorporate a lipid extract of Skeletonema into the composition of Briand or to teach the extracts of Briand as lipid extracts, as taught by Winget, because of the expectation of achieving a product that treats existing skin aging and protects again further skin aging by UV damage (effect of antiinflammatories).

Since a compound and its properties are inseparable, the Skeletonema of the combined references have the properties of promoting intercellular communication via gap junctions of keratinocytes, fibroblasts and skin preadipocytes and of promoting intercellular communication to promote the formation of connexin.

The claims are directed to a method of applying a composition comprising an extract of Skeletonema to the skin. Any properties exhibited by or benefits provided the composition are inherent and are not given patentable weight over the prior art. A chemical composition and its properties are inseparable. Therefore, if the prior art teaches the identical chemical structure, the properties Applicant discloses and/or claims are necessarily present. In re Spada, 911 F.2d 705, 15 USPQ 1655, 1658 (Fed. Cir. 1990). See MPEP 2112.01. The burden is shifted to Applicant to show that the prior art product does not inherently possess the same properties as instantly claimed product. The prior art teaches application to the skin of compositions containing the same components as instantly claimed, which would inherently treat aging or promote the activity of a cosmetic agent, as instantly claimed. Applicant has not provided any evidence of record to show that the prior art compositions do not exhibit the same properties as instantly claimed.

The Examiner respectfully points out instant claims 63, 65-76, 80-91 are product-by-process claim. Even though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claims is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process. In re Thorpe, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985). See MPEP 2113.

Regarding claims 76 and 91, it is respectfully pointed out that for the purposes of searching for and applying prior art under 35 USC 102 and 103, absent a clear indication in the specification or

claims of what the basic and novel characteristics actually are, "consisting essentially of" will be construed as equivalent to comprising. If an applicant contends that additional steps or material in the prior art are excluded by the recitation of "consisting essentially of", applicant has the burden of showing that the introduction of additional steps or components would materially change the characteristics of applicant's invention. See MPEP 2111.03.

Applicants respectfully traverse this rejection. To establish a *prima facie* case, the PTO must satisfy three requirements. First, the prior art relied upon, coupled with the knowledge generally available in the art at the time of the invention, must contain some suggestion or incentive that would have motivated the skilled artisan to modify a reference. *In re Fine*, 837 F.2d 1071, 1074, 5 U.S.P.Q.2d 1596, 1598 (Fed. Cir. 1988). Second, the proposed modification of the prior art must have had a reasonable expectation of success, determined from the vantage point of the skilled artisan at the time the invention was made. *Amgen, Inc. v. Chugai Pharm. Co.*, 927 F.2d 1200, 1209, 18 U.S.P.Q.2d 1016, 1023 (Fed. Cir. 1991). Lastly, the prior art reference must teach or suggest all the limitations of the claims. *In re Wilson*, 424 F.2d 1382, 1385, 165 U.S.P.Q. 494, 496 (C.C.P.A. 1970).

a. The present invention.

The present invention, as currently amended, is directed to a method for promoting intercellular communication of skin cells, comprising the application, to the appropriate skin areas of a person in need thereof, of an effective amount of at least one

lipid extract of the alga Skeletonema.

b. Cited references.

Briand discloses the use of microscopic algal extracts for the preparation of pharmaceutical, cosmetic, feed or agricultural compositions.

Winget discloses pharmaceutical compositions of anti-inflammatory microalgal lipid preparations containing monogalactosyl dieicosapentaenoyl glycerol and processes for making said preparations.

c. Differences between present invention and the cited references.

Applicants respectfully submit that none of the references, either alone or in combination, teach, or suggest, a means for promoting interconnection of skin cells, or intercellular communication of skin cells, as is presently claimed. The references do not contain any suggestion or motivation that they be combined in the manner suggested in the Office Action.

Therefore, Applicants respectfully request the Examiner to reconsider and withdraw the rejection.

CONCLUSION

Based upon the above amendments and remarks, the presently claimed subject matter is believed to be novel and patentably distinguishable over the references of record. The Examiner is therefore respectfully requested to reconsider and withdraw the objection and rejections and allow all presently pending claims. Favorable action with an early allowance of the claims pending in this application is earnestly solicited.

Respectfully submitted,

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